APR 2 7 2012

510(k) Summary

Submitter information

Company name	Materialise N.V.
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Additional contact person	Toon Lenaerts
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Submission information

Trade Name	SurgiCase, SurgiCase Connect
Common Name	Image processing system
Classification Name	Radiological image processing system
Product code	LLZ (21 CFR 892.2050)
Classification panel	Radiology
Device classification	Class II

Device information

Description and functioning of the device

The Materialise **SurgiCase** system is a software medical device to transfer and to segment imaging information from a medical scanner such as a CT or MRI scanner. It allows for pre-surgical simulation and evaluation of implant placement and surgical treatment options.

SurgiCase Connect is a medical device for pre-surgical simulation and evaluation of surgical treatment options. This includes transferring, visualizing and editing medical data.

Based on a pre-surgical software plan the patient specific templates - SurgiCase Guides can be manufactured to fit a specific patient. SurgiCase Guides are not a part of this premarket notification submission.

Indications for Use

The **SurgiCase** system is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner. It is also intended as pre-operative software for simulating / evaluating implant placement and surgical treatment options.

SurgiCase Connect for iPad is a component of the SurgiCase system and intended to be used as a software interface to assist in pre-operative planning by simulation / evaluation of surgical treatment options.

Predicate device

Trade or proprietary or model name	SurgiCase
510(k) number	K073449
Decision date	16/APR/2008
Product code	LLZ
Manufacturer	Materialise

Summary of technological characteristics

The **SurgiCase Connect** for iPad is considered to be substantially equivalent in intended use, performance characteristics, design and function to the predicate SurgiCase system.

Performance data

Non-clinical testing

The **SurgiCase Connect** for iPad has been validated for its intended use to determine substantial equivalence to the predicate device.

Clinical testing

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Alexandra Razzhivina
Regulatory Officer
Materialise NV
Technologielaan 15
LEUVEN 3001
BELGIUM

APR 2 7 2012

Re: K113599
Trade/Device Name: SurgiCase system (SurgiCase, SurgiCase Connect)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 6, 2012
Received: March 8, 2012

Dear Ms. Razzhivina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113599

Device Name: **SurgiCase system (SurgiCase, SurgiCase Connect)**

Indications for Use:

The **SurgiCase** system is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner. It is also intended as pre-operative software for simulating / evaluating implant placement and surgical treatment options.

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Prescription Use _ X ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __ _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) K113599